DETAILED ACTION

Status of the Claims

Claims 1-13, 18, 19, 21-23, 31, and 32 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Election/Restrictions

In the response of Apr. 8, 2010, applicants elected the following species without traverse:

Microsphere polymer: copolymers of polyesters

Matrix polymer: silicone copolymers

In the response, applicants have stated that claims 1-13, 18, 19, 21-23, 31, and 32 read on the elected species.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided, were not provided in English, or did not have a proper publication date.

Specification (Abstract)

The abstract of the disclosure is objected to because the abstract is not adequately descriptive. The current abstract is essentially a one-sentence restatement of the title of the application. 37 CFR 1.72(b) states that: "...The purpose of the abstract is to enable the United States Patent and Trademark Office and the public

generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." No additional information is currently provided in the abstract that one could not obtain from the title of the application. A new abstract (150 words or less) is required that is sufficiently detailed as to provide general information about the precise nature of the invention to which the claims are directed. New matter is not permitted in the revised abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 18, 19, 21-23, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 3 (and the claims dependent thereon) are indefinite in the recitation "an effective amount". The term/phrase "effective amount" is subjective and is not defined in a limiting way in the specification. This term begs the question, "Effective to do what?" Effective to, for example, treat pain, cause euphoria, induce unconsciousness, enter the bloodstream, etc. The specification does not provide a sufficient standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, one of ordinary skill in the art could reasonably construe "effective amount" to be any of a number of parameters. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in

the specification, the metes and bounds of these claims are indefinite.

B. Claim 22 is also indefinite in the recitation "rubber-like". What compounds and/or structural features are encompassed by "rubber-like" are unknown. This situation is analogous to the addition of the word "type" to an otherwise definite expression. See MPEP § 2173.05(b)(E). The addition of the word “type” to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 12, 13, 18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by GRANGER (U.S. 5,149,538; Issued Sep. 22, 1992; Ref. AA on IDS dated 12/26/06).

1. Granger discloses misuse-resistive transdermal opioid dosage forms (title; abstract) that are structurally identical to those instantly claimed. For example, Fig. 3 of Granger illustrates an embodiment wherein an opioid antagonist is encapsulated and dispersed within a medium (i.e. a matrix) containing the opioid drug (Fig. 3; col. 6, lines 13-19). In particular, Granger teaches that the antagonist particles may be microencapsulated (claim 1, element d). Note the definition of "microsphere" in the

instant specification (par. [0032]) encompasses a variety of particles. Granger further recognizes the benefit of making the antagonist difficult to separate from the agonist (Fig. 3; col. 1, lines 55-59; col. 2, lines 12-13; col. 6, lines 11-13; col. 7, lines 53-56). Naltrexone is the preferred antagonist (col. 2, lines 65-68). Thus, Granger discloses the patches (*and inventive concept*) of the claimed invention, anticipating claims 1, 5, 8, 12, 13, 18, and 21.

2. Regarding claims 5 and 21, Granger teaches that the opioid drug is dispersed in a polymeric matrix (delivery means) (col. 3, line 48 to col. 4, line 20).

3. Regarding claim 8, the MPEP states that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Furthermore, the MPEP states that if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional

steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6, 7, 9-11, 19, 22, 23, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger in view of GALE (U.S. 2004/0013716; Filed Apr. 22, 2003).

4. The teachings of Granger are presented *supra*. While Granger teaches microencapsulation of the antagonist, Granger is silent to the actual mean diameter of the particles. However, Given the teachings of Granger and the related art, selection of antagonists microparticles having a mean diameter as instantly claimed would have been routine to the skilled artisan.

5. For example, Gale discloses transdermal analgesic systems with reduced abuse potential (title; abstract). Gale teaches that the antagonist may be in the form of coated beads or spheres, which may be in any size, but are preferably small sized, preferably less than 10 microns (par. [0076]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use microspheres in small sizes on the order of microns as taught by Gale. One would have been motivated to do so since Granger does not explicitly specify the size of the encapsulated antagonist microparticles, and since Gale teaches that microspheres used for the exact same purpose are preferably small, such as less than 10 microns.

6. Regarding claims 9-11 and 19, Granger teaches microencapsulated particles, which any skilled artisan would know refers to particles in the micron size range (e.g. on the order of from 0.1-1000 microns). Additionally, Gale teaches that the beads may be any size. Further, the instant claims all use the term "about" in reference to the claimed diameter ranges, which therefore have significant leeway. Moreover, a *prima facie* case

of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). In this case, it is the examiner's position that an artisan would understand Granger's teachings to encompass the claimed range, but in any case, there is no evidence that a difference in size would lead to any unexpected properties or effects. In particular, it is noted that ranges of 1-500 microns are claimed throughout the instant claims, in various increments. Thus, particles within any of these sizes all appear to be interchangeable alternatives, absent evidence to the contrary. The prior art teachings render the claimed ranges obvious.

7. Regarding claims 6 and 7, Granger teaches that a barrier means separates the antagonist substance from the opioid (col. 5, lines 39-40), and teaches polyester copolymers (elected species) such as, *inter alia*, polysiloxane-polycarbonate copolymers, polycarbonates, cellulose esters, and combinations thereof (col. 5, lines 45-68). Thus, it would be obvious to use any of these types of polymers, which are directly taught by Granger for the exact use instantly claimed.

8. Regarding claims 22 and 23, Granger teaches that the opioid matrix delivery means can comprise materials such as, *inter alia*, silicone elastomers and silicone copolymers (elected species) (col. 3, lines 52-64).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 10/476,601

Claims 1-13, 18, 19, 21-23, 31, and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 32, and 33 of copending Application No. 10/476,601 in view of Granger and Gale. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '601 claims anticipates or renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite certain polymer materials and antagonist particle sizes. However, these elements, and thus the entire scope of the instant claims, are rendered obvious by Granger and Gale, as discussed above.

U.S. Patent Application No. 11/865,387

Claims 1-13, 18, 19, 21-23, 31, and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11/865,387 in view of Granger and Gale. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '387 claims anticipates or renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite certain polymer materials and antagonist particle sizes. However, these elements, and thus the entire scope of the instant claims, are rendered obvious by Granger and Gale, as discussed above. Furthermore, selection of the appropriate form(s) of a drug is within the purview of the skilled artisan. Moreover, Granger teaches the claimed forms.

Conclusion

Claims 1-13, 18, 19, 21-23, 31, and 32 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KSO/

/Lakshmi S Channavajjala/
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